

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/502,403
				Filing Date	§ 371(c) Date: June 20, 2005
				First Named Inventor	LARA OCHOA, José Manuel Francisco
				Art Unit	1611
				Examiner Name	Rae, Charlesworth E.
Sheet	1	of	1	Attorney Docket Number	2099.0090000/PAJ/LMB

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
/TL/	US1	3,072,527	01-08-1963	Cohen	
↓	US2	5,416,105	05-16-1995	Sato <i>et al.</i>	
	US3	5,955,106	09-21-1999	Moeckel <i>et al.</i>	
	US4	6,011,049	01-04-2000	Whitcomb	
	US5	6,031,004	02-29-2000	Timmins <i>et al.</i>	
	US6	6,303,146 B1	10-16-2001	Bonhomme <i>et al.</i>	
	US7	6,348,469 B1	02-19-2002	Seth	
	US8	6,499,984 B1	12-31-2002	Ghebre-Sellassie <i>et al.</i>	
	US9	6,682,759 B2	01-27-2004	Lim <i>et al.</i>	
	US10	6,890,957 B2	05-10-2005	Chandran <i>et al.</i>	
↓	US11	2003/0187074 A1	10-02-2003	Hussain <i>et al.</i>	
	US12	2004/0219212 A1	11-04-2004	Castan <i>et al.</i>	
/TL/	US13	2007/0264331 A1	11-15-2007	Regalado <i>et al.</i>	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
/TL/	FP1	WO 97/17975 A1	05-22-1997	Istituto Gentili S.P.A.		
↓	FP2	WO 00/40233 A1	07-13-2000	Hexal AG		Abs ISR
	FP3	WO 01/32158 A2	05-10-2001	Bristol-Myers Squibb Company		
↓	FP4	WO 03/061643 A1	07-31-2003	Laboratorios Silanes, S.A. de C.V.		Abs
/TL/	FP5	WO 2004/045622 A1	06-03-2004	Ranbaxy Laboratories Limited		

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NON PATENT LITERATURE DOCUMENTS			
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/TL/ ↓	NPL1	ABBINK, E.J., <i>et al.</i> , "Vascular effects of glibenclamide vs. glimepiride and metformin in Type 2 diabetic patients," <i>Diabet. Med.</i> 19:136-143, Blackwell Science (February 2002)	
	NPL2	BRESSLER, R., and JOHNSON, D.G., "Pharmacological Regulation of Blood Glucose Levels in Non-Insulin-Dependent Diabetes Mellitus," <i>Arch. Intern. Med.</i> 157:836-848, American Medical Association (1997)	
	NPL3	CEFALU, W.T., <i>et al.</i> , "Insulin Sensitivity is Improved After Glipizide GITS Mono-Therapy and in Combination with Metformin," <i>Diabetologia</i> 39:A231, Springer Verlag (1996)	
	NPL4	CEFALU, W.T., <i>et al.</i> , "Combination Glipizide GITS/Metformin Normalizes Glucose and Improves Insulin Sensitivity in Hyperinsulinemic Moderately Well Controlled NIDDM," <i>Diabetes</i> 45:201A, American Diabetes Association (1996)	
	NPL5	CHARPENTIER, G., <i>et al.</i> , "Improved glycaemic control by addition of glimepiride to metformin monotherapy in Type 2 diabetic patients," <i>Diabet. Med.</i> 18:828-834, Blackwell Science (October 2001)	
	NPL6	CROUSE III, J.R., <i>et al.</i> , "Effects of Combination Glipizide GITS/Metformin Treatment on Oxidizability of LDL in Non-Insulin Dependent Diabetes Mellitus," <i>Circulation</i> 94:I-508, Lippincott Williams & Wilkins (1996)	
	NPL7	DAGOGO-JACK, S., and SANTIAGO, J.V., "Pathophysiology of Type 2 Diabetes and Modes of Action of Therapeutic Interventions," <i>Arch. Intern. Med.</i> 157:1802-1817, American Medical Association (1997)	
	NPL8	DEFRONZO, R.A., "Pharmacologic Therapy for Type 2 Diabetes Mellitus," <i>Ann. Intern. Med.</i> 131:281-303, American College of Physicians (1999)	
	NPL9	DEFRONZO, R.A., <i>et al.</i> , "Efficacy of Metformin in Patients with Non-Insulin-Dependent Diabetes Mellitus," <i>N. Engl. J. Med.</i> 333:541-549, Massachusetts Medical Society (1995)	
	/TL/	NPL10	GARBER, A.J., <i>et al.</i> , "Efficacy of Metformin in Type II Diabetes: Results of a Double-Blind, Placebo-controlled, Dose-Response Trial," <i>Am. J. Med.</i> 102:491-497, Excerpta Medica, Inc. (1997)

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/TL/ ↓	NPL11	GONZÁLEZ-ORITZ, M., <i>et al.</i> , "Eficacia y seguridad de la terapia hipoglucemiante oral combinada de glimepirida más metformina en una sola forma farmacéutica en pacientes con diabetes mellitus tipo 2 y falla secundaria a monoterapia con glibenclamida," <i>Rev. Invest. Clin.</i> 56:327-333, Instituto Nacional de la Nutrición (May-June 2004)	√	
	NPL12	English Language Translation of GONZÁLEZ-ORITZ, M., <i>et al.</i> , "Efficacy and safety of glimepiride plus metformin in a single presentation, as combined therapy, in patients with type 2 diabetes mellitus and secondary failure to glibenclamide, as monotherapy," <i>Rev. Invest. Clin.</i> 56:327-333, Instituto Nacional de la Nutrición (May-June 2004)		
	NPL13	GONZÁLEZ-ORITZ, M., <i>et al.</i> , "Efficacy of glimepiride/metformin combination versus glibenclamide/metformin in patients with uncontrolled type 2 diabetes mellitus," <i>J. Diabetes Complicat.</i> , Elsevier Science Publishing Company, 4 pages, Article in Press, uncorrected proof (September 2008)		
	NPL14	GOMIS, R., <i>et al.</i> , "Appropriate Timing of Glimepiride Administration in Patients with Type 2 Diabetes Mellitus," <i>Endocrine</i> 13:117-121, Endocrine Society (2000)		
	NPL15	HERMANN, L.S., <i>et al.</i> , "Therapeutic Comparison of Metformin and Sulfonylurea, Alone and in Various Combinations," <i>Diabetes Care</i> 17:1100-1109, American Diabetes Association (1994)		
	NPL16	HIGGINBOTHAM, L. and MARTIN, F.I.R., "Double-Blind Trial of Metformin in the Therapy of Non-Ketotic Diabetics," <i>Med. J. Aust.</i> 2:154-156, Australian Medical Publishing Company Limited (1979)		
	NPL17	HOLSTEIN, A., <i>et al.</i> , "Lower Incidence of Severe Hypoglycaemia in Type 2 Diabetic Patients Treated with Glimepiride Versus Glibenclamide," <i>Diabetologia</i> 43:A 40, Springer Verlag (2000)		
	NPL18	MÜLLER, G., <i>et al.</i> , "Differential interaction of glimepiride and glibenclamide with the β -cell sulfonylurea receptor," <i>Biochim. Biophys. Acta</i> 1191:267-277, Elsevier Pub. Co. (1994)		
	NPL19	ROSENSTOCK, J., <i>et al.</i> , "Glimepiride, a New Once-Daily Sulfonylurea," <i>Diabetes Care</i> 19:1194-1199, American Diabetes Association (1996)		
	/TL/	NPL20	SATO, J., <i>et al.</i> , "Comparison between effects of glimepiride and glibenclamide on <i>in vivo</i> insulin action," in <i>Proceedings of the Fourth International Symposium on Treatment of Diabetes Mellitus, Nagoya, 26-27 October 1993</i> , Sakamoto, N., <i>et al.</i> , eds., Excerpta Medica, Amsterdam, Netherlands, pp. 341-348 (1994)	
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/TL/	NPL21	SCHEEN, A.J., and LEFÈBVRE, P.J., "Oral Antidiabetic Agents. A Guide to Selection," <i>Drugs</i> 55:225-236, ADIS Press (1998)	
	NPL22	SIFTON, D., ed., "Anzemet® Injection," in <i>Physicians Desk Reference</i> , 54 th Ed., Medical Economics Company, Montvale, NJ, pp. 1349-1352 (2000)	
	NPL23	SONNENBERG, G.E., <i>et al.</i> , "Short-Term Comparison of Once- Versus Twice-Daily Administration of Glimepiride in Patients with Non-Insulin-Dependent Diabetes Mellitus," <i>Ann. Pharmacother.</i> 31:671-676, Harvey Whitney Books Company (1997)	
	NPL24	VIGNERI, R., <i>et al.</i> , "Treatment of NIDDM Patients with Secondary Failure to Glyburide: Comparison of the Addition of Either Metformin or Bed-Time NPH Insulin to Glyburide," <i>Diabete. Metab.</i> 17:232-234, Masson (1991)	
	NPL25	International Search Report for International Application No. PCT/MX02/00003, mailed on January 30, 2003, European Patent Office, Rijswijk, Netherlands	
	NPL26	International Preliminary Examination Report for International Application No. PCT/MX02/00003, completed on April 28, 2004, European Patent Office, Munich, Germany	
↓ /TL/	NPL27	SHIMPI, R.D., <i>et al.</i> , "Comparison of effect of metformin in combination with glimepiride and glibenclamide on glycaemic control in patient with type 2 diabetes mellitus," <i>Int. J. PharmTech Res.</i> 1:50-61, Sphinx Knowledge House (January-March 2009)	

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